Attorney Docket No. 24222-X3

DRUG DELIVERY SYSTEMS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to an encapsulation process, and in particular, an alternate encapsulation process for concentrating pharmaceuticals using compression.

2. Description of the Prior Art

Various types of chewable articles are known in commerce. These articles include food items such as food items, confectionery items and chewing gum. The chewable articles often include various types of active agents or ingredients within the chewable articles. Examples of such active ingredients include flavors, sweeteners, colors, pharmaceuticals, vitamins, minerals, and other effervescent agents.

It has been known in the art of food stuff, confectionery and chewing gum preparation to provide protection to the active ingredients by the use of protection systems, including providing a protective coating around the active ingredient or encapsulating the active ingredient. Such protective systems have been employed for various reasons, such as for protection of the active ingredient, both while on the shelf and during use, and for prolonged release in the oral cavity.

It is known in the art to protect active ingredients by encapsulating the active ingredient prior to introducing the ingredient into a final product. Some of the major classifications of encapsulation technology include liquid suspending media (water-in-oil emulsions and oil-in-water emulsions), interfacial and in situ polymerization, solvent

evaporation from emulsions, desolvation, complex coacervation, polymer and polymer incompatibality, gelation, and pressure extrusion. One of skill in the art will be familiar with each of these classifications.

Schobel, U.S. Patent No. 4,568,560, discloses encapsulated fragrances and flavors for use in denture cleanser compositions. Schobel discloses encapsulating a solid particulate flavoring agent or fragrance with a film of an acrylic polymer and ethylcellulose. The encapsulation is accomplished utilizing a fluidized bed of the flavoring agent or fragrance.

Yang, U.S. Patent No. 4,740,376, discloses encapsulating an active ingredient in a solvent free encapsulation composition which includes a blend of a high molecular weight polyvinyl acetate and a hydrophilic plasticizer. The active ingredient is protected from deterioration due to moisture and is provided with controlled release for use in a product to be ingested by a mammal.

Cherukuri et al., U.S. Patent No. 4,981,698, discloses a delivery system for sweeteners that comprises a first high intensity sweetener encapsulated in a first core coating, and a second outer hydrophilic coating containing up to the solubility limit of the second coating of a second sweetener. The delivery system offers enhanced up front sweetness intensity in combination with prolonged sweetness duration, and improved protection and stability of the sweetener.

Cherukuri et al., U.S. Patent No. 5,004,595, discloses a free-flowing particulate delivery system for providing enhanced flavor and sweetness to comestible products. The delivery system includes an encapsulating matrix that protects flavor in a core.

Cherukuri et al., U.S. Patent No. 5,266,335, discloses

microencapsulated flavoring agents and methods for preparing the same. The microencapsule comprises a flavoring agent and a resin in the core, and a coating layer over the core. The core is encapsulated by emulsion of a flavoring agent and a resin with a coating layer prepared by complex coacervation of a mixture of two or more colloidal materials.

Kehoe, U.S. Patent No. 4,975,270, discloses elastomer encased active ingredients. The active ingredients are physically encased in non-porous, chewable particles of elastomer. The particles are then incorporated into articles of commerce.

There are a number of disadvantages when using the traditional encapsulation processes to encapsulate active ingredients. The disadvantages include the need for heat and moisture in order to properly form the encapsulated final product. Also, most encapsulation methods are complex and consume large amounts of time in order to obtain the final encapsulated product. Further, current encapsulated ingredients vary in size from nanometers to about 400 microns, and the active ingredients are not uniformly distributed throughout the encapsulated product.

Therefore, there remains a need for an alternate encapsulation method for providing a product with high levels of active ingredients and in which water is not needed during the encapsulation process, nor is heat an essential feature of the encapsulation process. There also remains a need for an alternate encapsulation method which produces capsules with uniform active ingredient content throughout the product, and that can withstand mechanical pressure both in the processing of the capsule and in the chewing of the product in the mouth so that the active ingredients are released in the stomach of the